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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,912	03/27/2006	Dominique M Freeman	38187-2783.US	8064

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Goodwin Procter LLP
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EXAMINER	
D'ANGELO, MICHAEL J	
ART UNIT	PAPER NUMBER
3735	

NOTIFICATION DATE	DELIVERY MODE
10/28/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/540,912	FREEMAN ET AL.	
	Examiner	Art Unit	
	MICHAEL D'ANGELO	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :06/27/2005;03/16/2007;04/02/2007;04/18/2008;06/10/2008;6/23/2008;08/26/2008;10/17/2008;11/06/2008;01/14/2009;03/26/2009;05/27/2009;09/15/2009;12/10/2009;03/09/2010; 1/25/2010, 9/21/2010

DETAILED ACTION

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Information Disclosure Statement

Applicant (or the assignee of this application if the assignee has undertaken the prosecution of the application) is required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

Applicant has cited an extraordinary number of references in the submitted information disclosure statements. In accordance with 37 CFR 1.105 and MPEP 704, applicant (or the assignee) is required (1) to provide an explanation as to why each reference has been cited, (2) what specific feature in each reference is pertinent to respective limitations in the claims, and (3) how each reference cited defines over the claim(s) wherein each of (1), (2), and (3) should be meaningfully different. A simple statement that each of the references are relevant will not be sufficient. If applicant deems certain of the references cited to not be relevant, applicant should submit a new IDS containing only references that are pertinent to the examination of this application. In so doing, applicant is still required to provide each of (1), (2), and (3) above. This requirement is reasonably necessary for examination in

light of the extraordinary number of cited references by applicant. Because the applicant (or the assignee) has presumably inspected all of the listed citations, it is reasonable to require the applicant to provide the information needed so that the most relevant citations are fully considered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 7,198,606. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-16 of the current application are merely broader in scope than those of U.S. Patent No. 7,198,606.

4. Claim 22 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 15 of U.S. Patent No. 7,141,058. Although the conflicting claims are not identical, they are not patentably distinct from each other because although claim 15 of U.S. Patent No. 7,141,058 fails to disclose using an electrochemical sensor with a potentiometric technique this is very well known in the art for determining analyte concentrations.

5. Claims 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 of U.S. Patent No. 7,713,214. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1 of the current application are merely broader in scope than those of U.S. Patent No. 7,713,214.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1-5, 10, 11, and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Moerman et al. (US 6,706,159).

Regarding claims 1 and 3, Moerman discloses a cartridge with a radial shape and a plurality of analyte detecting members (elements 84 and 814, se figure 8C).

Regarding claim 2, Moerman discloses where the cartridge does not contain penetrating members (see figure 8C, the penetrating members are located on element 87).

Regarding claim 4, Moerman discloses where the cartridge fits in a metering device (see figures 8A-B where element 84 fits within element 81).

Regarding claim 5, Moerman discloses where only a working electrode is covered with glucose oxidase (column 5, lines 24-26 and column 9, lines 4-7).

Regarding claim 10, Moerman discloses using an amperometric measurement technique (column 10 line 37).

Regarding claim 11, Moerman discloses a mesh positioned over the detection members (mesh strips 94, the examiner notes that this mesh can be configured to spread fluid over the detection member even though there is no specific disclosure to its function).

Regarding claim 17, Moerman discloses a cartridge with a plurality of sample chambers (column 7, line 56 to column 8, line 18, where the chambers are formed by the stacking of elements 84, 85, and 86), a plurality of analyte detecting members (elements 814), where the detecting members form a portion of a wall of the chamber (see figure 8C, elements 814 make up part of the bottom of the sample chamber when constructed).

Regarding claim 18, Moerman discloses the cartridge comprising a connector disc (85) and detecting member disc (84).

Regarding claim 19, Moerman discloses a cartridge with a plurality of sample chambers (column 7, line 56 to column 8, line 18, where the chambers are formed by the stacking of elements 84, 85, and 86), a plurality of analyte detecting members (elements 814), wherein said chambers are adjacent an outer periphery of the cartridge (see figure 8C, the detecting members can be considered a combination of elements

814, 816, and 818 which are located on the rim of disc 84), and at least one opening in of said chambers leading fluid toward the detecting member (column 8, lines 19-43).

8. Claim 21 is rejected under 35 U.S.C. 102(e) as being anticipated by Heller et al. (US 6,576,101).

Regarding claim 21, Heller discloses collecting a sample of 500 nL or less (column 5, lines 50-67), and covering an electrochemical sensor with the sample for determining an analyte concentration using a potentiometric technique (column 1 line 59, to column 2 line 14).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 7, 9, 12, 22-23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moerman et al. (US 6,706,159) in view of Gough (US 2002/0156355).

Regarding claims 7 and 12, Moerman fails to disclose where the analyte members have differing sensitivity ranges for enhancing the overall sensitivity of the array when used on a sample and a hydrophilic membrane coating the sensor.

However, Gough discloses analyte members having differing sensitivity ranges for enhancing the overall sensitivity of the array when used on a sample and a hydrophilic membrane coating the sensor (paragraph 44).

13. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the analyte monitor of Moerman to include analyte members have differing sensitivity ranges for enhancing the overall sensitivity of the array when used on a sample and a hydrophilic membrane coating the sensor as taught by Gough in order to optimize the systems sensor response.

Regarding claim 9, Moerman discloses using a reference and working electrode where only the working electrode is covered with a redox mediator (column 9, lines 4-9), but fails to disclose using a counter electrode.

However, Gough discloses using a reference, working, and counter electrode (paragraph 34).

14. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the analyte monitor of Moerman to include using a reference, working, and counter electrode as taught by Gough as it would be a mere substitution of known electrode configurations.

Regarding claims 22-23, Moerman discloses a cartridge with a plurality of cavities (column 7, line 56 to column 8, line 18, where the cavities are formed by the stacking of elements 84, 85, and 86), a plurality of analyte detecting members defining an array (elements 814), but fails to disclose where the analyte members have differing sensitivity ranges for enhancing the overall sensitivity of the array when used on a sample.

However, Gough discloses analyte members having differing sensitivity ranges for enhancing the overall sensitivity of the array when used on a sample (paragraph 44).

15. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the analyte monitor of Moerman to include analyte members have differing sensitivity ranges for enhancing the overall sensitivity of the array when used on a sample as taught by Gough in order to optimize the systems sensor response.

Regarding claim 24, Moerman discloses a cartridge with a plurality of cavities (column 7, line 56 to column 8, line 18, where the cavities are formed by the stacking of elements 84, 85, and 86), an electric penetrating driver (column 7, lines 15-25 and column 8, lines 19-43, the examiner notes that if the system is automated there must be

an electrical actuator for rotating cam ring 86 to drive the penetrating members), A plurality of penetrating members housed in the cavities and individually moveable by said driver (see figure 8G, column 8, lines 19-43), a plurality of analyte detecting members defining an array (elements 814) where each cavity has one analyte array (see figures 8C-F), but fails to disclose where the analyte members have differing sensitivity ranges for enhancing the overall sensitivity of the array when used on a sample.

However, Gough discloses analyte members having differing sensitivity ranges for enhancing the overall sensitivity of the array when used on a sample (paragraph 44).

16. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the analyte monitor of Moerman to include analyte members have differing sensitivity ranges for enhancing the overall sensitivity of the array when used on a sample as taught by Gough in order to optimize the systems sensor response.

17. Claims 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moerman et al. (US 6,706,159) in view of Daddona et al. (US 6,091,975)

Regarding claim 6, Moerman fails to disclose making the electrodes from Ag or Ag/Cl and using a counter electrode.

However, Daddona discloses disclose making the electrodes from Ag or Ag/Cl and using a counter electrode (column 1, lines 35-42 and column 4, line 45).

18. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the analyte monitor of Moerman to include making the electrodes

from Ag or Ag/Cl and using a counter electrode as taught by Daddona as it would be a mere substitution of known electrode configurations and materials.

19. Claims 8 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moerman et al. (US 6,706,159) in view of Aceti et al. (US 2002/0087056).

Regarding claim 8, Moerman discloses using a small sample (column 11, lines 18-20, but fails to disclose a specific volume.

However, Aceti discloses a system where 300nL are used (paragraph 35).

20. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the analyte monitor of Moerman to include only using 300nL sample in order to create a compact system with small sample chambers for analysis.

Regarding claims 13-16, Moerman discloses a miniature sized cartridge (see figures 8A-G, the examiner notes that based on the size shown in figure 8A the cartridge could have the same volume of 4.53 cm cubed), but fails to disclose the volume of the detecting members.

However, Aceti discloses a system where more than 160 sample chambers are used (paragraph 36, the examiner notes that in the combination the density would be higher than 4.53/50 since 160 or more sample chambers would be used).

21. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the analyte monitor of Moerman to include having 160 or more sample chambers as taught by Aceti in order to provide a longer lasting system for use.

22. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moerman et al. (US 6,706,159) in view of Heller et al. (US 6,576,101).

Regarding claim 20, Moerman fails to disclose using no more than 1 uL.

However, Heller discloses sampling using no more than 1 uL (column 5, liens 50-67).

23. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the analyte monitor of Moerman to incorporate sampling by using no more than 1 uL as taught by Heller in order to reduce pain for the patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL D'ANGELO whose telephone number is (571) 270-7112. The examiner can normally be reached on Monday-Friday 9-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner, Art Unit 3735

/M. D./
Examiner, Art Unit 3735